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Shinichi Yamada

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EXAMINER

YU, GINA C

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/857,495	Applicant(s) YAMADA ET AL.	
	Examiner GINA C. YU	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the appeal brief filed on April 27, 2009, PROSECUTION IS HEREBY REOPENED. New rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 19, 27-31, 35-54, 56, 57, 61-64, 69-71, 74, 79-81 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lambers et al. (US 5693677) in view of Oblong et al. (US 5939082) and Young et al. (Fluid Mechanics, 2001, 2nd ed., John Wiley & Sons, pp. 11-13).

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Lambers teaches a cosmetic emulsion comprising a ceramide III derivative. The reference teaches that isocetyl alcohol is used to dissolve ceramide III and its derivative dissolve, and adding ethanol, propylene glycol or butylene glycol further enhances the solubility. See Example 2; col. 3, lines 46 – 53. The suitable vehicles for the invention include water and liquids. See col. 4, lines 8 - 13. With respect to claim 57, "a composition to be applied to the hair" denotes the intended future use of the product made by the claimed method, and is not viewed patentably distinct from the claimed method of making a skin cosmetic.

While Lambers does not teach adding cationic surfactant, it is a well-known practice in cosmetic art to use hydrophilic cationic surfactants to disperse hydrophobic materials and stabilize oil-in-water emulsions, as shown in Oblong. See col. 13, lines 58 – col. 16, line 6. The reference also teaches that cosmetic compositions with low viscosity can be made with viscosity of about 50 centistokes or less, or most preferably about 5 centistokes or less. See col. 8, lines 20-25.

Although the low-viscous fluid cosmetic of Oblong is expressed in centistokes, one of ordinary skill in the art would have known how to determine the viscosity of such composition in centipoise. Young teaches the dynamic viscosity of a fluid is directly proportionate to the kinematic viscosity and density (i.e., dynamic viscosity = kinematic viscosity / density). See p. 11-13. For example, for water, whose density and dynamic viscosity are 1 g/cm³ and 1 cP at 25 °C, respectively, the kinematic viscosity is 1 cSt.

It would have been obvious to a skilled artisan to modify the cosmetic composition of Lambers by incorporating hydrophilic cationic surfactants as motivated

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by Oblong because the latter teaches that the cationic surfactants are used to stabilize oil-in-water emulsions. Since Lambers teaches to make the final products in the form of liquid and Oblong teaches making low-viscosity emulsions, the skilled artisan would have had a reasonable expectation of successfully producing a low viscosity fluid emulsion which contains ceramide III dissolved in liquid fatty alcohol such as isocetyl alcohol, stabilized by surfactants such as hydrophilic cationic surfactants.

Claims 19, 20, 27-30, 32, 33, 52-54, 56-58, 61, 64-66, 69, 72-76, and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergmann (US 6110450) in view of Flick (Cosmetic and Toiletry Formulations, 1995) and von Mallek (US 5888489 A).

The broadest claim in the instant case claims a liquid composition comprising at least one ceramide, at least one liquid fatty alcohol, and at least one cationic surfactant in a cosmetically acceptable medium, wherein the at least one fatty alcohol contains “no more than one hydroxyl group”, and wherein the composition has a viscosity of less than or equal to 1000 cPs. While the claim requires at least one liquid fatty alcohol with only one hydroxyl group in the composition, examiner construes the claim in such a way that it does not exclude the presence of liquid fatty alcohols with more than one hydroxyl groups. See MPEP § 2111.03; In re Grasselli, 713 F.2d 731, 218 USPQ 769 (Fed. Cir. 1983). The present specification does not support exclusion of diols or triols from the claimed composition.

Bergmann teaches a hair treatment and protection composition comprising at least one ceramide and/or glycosceramide in a cosmetically acceptable medium. See

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abstract. The reference teaches using 0.005-5 % and more preferably 0.01- 3 % by weight of ceramides and/or glycoceramides based on the weight of the composition.

See col. 5, lines 44 – 48. Cationic surfactants are taught in col. 6, lines 27-34.

Example 2 shows an aqueous formulation comprising oleoyldihydrosphingosine, cationic surfactants (components 1 and 4), and additives. See instant claims 57 and 58. The reference teaches the prior art products take the form of emulsions, dispersions, or solutions, in the form of fluid, spray or thickened liquid, while illustrating shampoo and conditioner products, thus suggesting obviousness in variation of the forms of the prior art. See col. 7, lines 27 – 33; instant claim 56. The methods for treating and protecting hair in instant claims 64, 65, 74, and 75 are obvious uses of the prior art hair care compositions.

Although Bergmann teaches generally teaches using fatty alcohols as a hair conditioning agents, as well as emollients, the reference does not disclose in sufficient specificity a liquid fatty alcohol with no more than one hydroxyl group. See col. 6, lines 50- 63.

Also, while Bergmann teaches the final product may be in the form of liquid, but does not specifically mention the viscosity of hair liquid composition.

Flick teaches a hair liquid formulation having a viscosity of 6 cps. See p. 65, Hair Liquid. The formulation contains 1 % of 2-hexyldecyl alcohol, which is a liquid branched fatty alcohol with one OH group. See instant claim 33. Varying the weight amount of the fatty alcohol to find an optimum weight range would have been within the skill of the art. See instant claim 34.

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Although Flick does not expressly disclose the utility of 2-hexyldecyl alcohol, von Mallek teaches this fatty alcohol is an emollient well known in hair care art at the time of the present invention. Von Mallek teaches conditioning shampoo compositions that employ as an emollient component fatty alcohol or fatty alcohol derivatives. The reference also teaches the emollient fatty alcohols are used in an amount ranging from about 0.5 to about 2.0 % by weight of the composition. See instant claim 34. The reference teaches the particularly preferred are Geurbet alcohols such as 2-hexyl decanol, 2-octyl decanol, 2-hexyl dodecanol, and 2-octyl dodecanol, which are branched liquid fatty alcohols with one OH group. Since von Mallek teaches 2-hexyl decanol and 2-octyl dodecanol of instant claim 30 are art-recognized functional equivalents, substituting one emollient for the other to make a similar hair care product would have been an obvious choice to a skilled artisan.

It would have been also obvious to the same skilled artisan to incorporate to the Bergmann hair care formulation a liquid fatty alcohol having one hydroxyl group such as 2-hexyl decanol as motivated by Flick and von Mallek because 1) Bergmann generally suggests using fatty alcohol as hair conditioning agent and adding emollients; 2) Flick exemplifies a specific hair treatment liquid product which utilizes 2-hexyl decanol; and 3) von Mallek teaches the fatty alcohol of the Flick formulation is a well known hair emollient. Since Bergmann teaches to make fluid or liquid compositions comprising fatty alcohols and ceramide and Flick teaches a hair liquid product having a viscosity of 6 cts, by combining the teachings of the references the skilled artisan would have had a reasonable expectation of successfully producing an emollient liquid hair

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treatment/protection composition that has a suitable viscosity for application to the hair.

Flick establishes that the use of the instant viscosity is known in the hair care art.

Claims 21-26, 34, 59, 60, 67, 68, and 77-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergmann, Flick, and von Mallek as applied to claims 19, 20, 27-30, 32, 33, 52-54, 56-58, 61, 64-66, 69, 72-76, and 82 as above, and further in view of Maubru (US 6312674 B1).

Bergmann and Flick fail to teach the specific ceramides of instant claims.

Maubru teaches oxidizing composition for bleaching or permanent reshaping hair, wherein the composition comprises ceramides disclosed in col. 3, line 21 – col. 16, line 13 in order to limit or prevent “deterioration in the mechanical properties of the hair”, particularly breaking of the hair and to obtain beautiful curls that withstand blow-drying and have good hold”. See col. 1, line 38 – col. 2, line 10. The reference specifically teaches bis(N-hydroxyethyl-N-cetyl)malonamide and 2-N-oleoylaminoctadecane-1,3-diol. See col. 5, lines 1 – 16. See instant claims 25-29. It is noted that oxidizing composition is used in “fixing step” in the permanent waving/straightening process. See col. 1, lines 1-29. Adding cationic polymers as a cosmetic additive is also suggested. See col. 5, lines 54 – 58; instant claim 19, 57, 64, and 74. The reference further teaches that the invention may contain other additives that are “known for their use in oxidizing compositions for bleaching or permanent reshaping of the hair”. The claimed process of treating is necessarily practiced when the composition is used according to the teaching in the prior art. Since the reference teaches that the composition may be

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in the form of lotion which may or may not be thickened, a low viscosity composition is also envisioned by Maubru. See col. 5, lines 44 – 45.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions of the combined references by substituting the ceramides of Bergmann with the ceramides of Bergmann, as motivated by the latter, because 1) both Bergman and Maubru teach using ceramides in hair protecting compositions; and 2) Maubru teaches that the specific ceramides therein limits and prevents breaking of hair and damage due to blow-drying, and produces beautiful curls. The skilled artisan would have been motivated to combine the references in expectation of successfully producing a hair care composition which protects the hair from damages of chemical treatment.

Claims 35-51, 62, 63, 70, 71, 80, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergmann, Flick, von Mallek and Maubru as applied to claims 19, 20, 27-30, 32, 33, 52-54, 56-58, 61, 64-66, 69, 72-76, and 82 above, and further in view of Dubief et al. (US 6120757) (“Dubief”).

The combined references fail to teach the specific cationic surfactants of instant claims.

Dubief teaches a hair protection composition comprising quaternary ammonium surfactants. See col. 4, line 51 – col. 6, line 2; see instant claims 35-51. Adding ceramides is taught in col. 6, line 39. The reference discloses that the invention can be used in permanent waving, straightening products, for washing or rinsing, or as a leave-in product. See col. 6, lines 50 – 58. Since the reference teaches that the composition

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may be in the form of aqueous dispersion and spray, making a light viscosity composition comprising the said quaternary ammonium surfactants is suggested by the prior art. See col. 6, lines 24-28.

It would have been obvious to a skilled artisan to modify the hair liquid composition of the combined references by substituting the cationic surfactant of Bergmann with those of Dubief, as motivated by the latter, because 1) both Bergmann and Dubief are directed to hair protection compositions comprising conditioning agents, 2) Bergmann teaches using cationic surfactants such as quaternary ammonium salts; and 3) Dubief teaches the specific types of quaternary ammonium salts which are useful for hair conditioning purposes.

Claims 35-51, 55, 62, 63, 70, 71, 80, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergmann, Flick, and von Mallek as applied to claims 19, 20, 27-30, 32, 33, 52-54, 56-58, 61, 64-66, 69, 72-76, and 82 above, and further in view of Ochiai et al. (US 5587155) ("Ochiai").

Bergmann fails to teach 18-methyleicosanoic acid and the quaternary ammonium cationic surfactants of instant claims.

Ochiai teaches hair-conditioning composition comprising 18-methyleicosanoic acid. See Table 3; Example 7; col. 1, line 54 – col. 2, line 54. The reference teaches that the fatty acid prevents hair damage and adds resilience to the hair, and renders moisturizing and hair conditioning effects. See col. 7, lines 36 – col. 8, line 60 for the application of the invention. Quaternary ammonium salts are taught in col. 3, line 36 – col. 5, line 51.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of the Bergmann references by adding a well known hair conditioning ingredient such as 18-methyleicosanoic acid as motivated by Ochiai because of the expectation of successfully producing a hair care products with hair protection, moisturizing, and conditioning effects.

Response to Arguments

Applicant's arguments filed on April 27, 2009 have been fully considered but they are moot in view of the new grounds of rejection in part and unpersuasive in part.

Lambers in view of Oblong

Citing the Background of the Invention section of Lambers on col. 1, lines 46-51, applicant asserts the reference teaches that various surfactants are "detrimental" to the penetration of the ceramide into the skin. Applicant also asserts the Lambers invention uses ceramide- 3 derivatives in order to avoid using surfactants. In response, examiner respectfully points out that those surfactants mentioned there in fact are specifically directed to glycerylethers only, which are not used in the present invention or the Lambers compositions. Examiner also takes the position that applicant mischaracterizes the Lambers invention because the utility of the prior art is to treat the skin damaged from particular type of surfactants (sodium dodecyl sulphate, an anionic surfactant, see col. 4, line 50), rather than formulating a surfactant-free product. In fact, example formulation employs cetareth-6, cetareth-25 which are polyethylene ether emulsifiers and penetration enhancers. Amphiphilic surface active agents are also taught as penetration enhancers useful for the invention. See col. 4, lines 23 – 33.

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Thus, applicant's assertion that Lambers teaches away from employing surfactants all together is erroneous, since the reference in fact teaches surfactants are required in order to stabilize the compositions and/or to enhance penetration of active ingredients (e.g., ceramides) to the skin.

In response to applicant's argument that the exemplary formulation provided by Lambers is in the form of a cream, applicant is reminded that Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). In this case, the reference also teaches liquid form of formulations in col. 4, lines 8 – 13, and does not in any way teach or suggest that the composition can be made only in the form of cream.

Applicant also asserts that the rejection is invalid allegedly because kinematic viscosity of "50 centistokes or less" as described in Oblong is "entirely different" from dynamic viscosity of "50 centipoises". As discussed above in the rejection, the conversion of the measurement is well within the skill of the art.

Bergmann in view of Flick

Applicant argues the previous rejection made in view of Bergmann and Flick fails to address the motivation to incorporate the monoalcohol of Flick. The argument is viewed persuasive and the rejection has been withdrawn. The arguments are now moot in view of the new grounds of rejection discussed above.

Bergmann and Flick and further in view of Maubru

Applicant asserts the rejection fails to cure the deficiencies of the previous rejection made in view of the Bergmann/Flick references. The arguments are moot in view of the withdrawal of the Bergmann/Flick rejection.

Bergmann, Flick, and Maubru and further in view of Dubief

Applicant asserts the rejection fails to cure the deficiencies of the previous rejection made in view of the Bergmann/Flick references. The arguments are moot as the Bergmann/Flick rejection has been withdrawn.

Bergmann and Flick and further in view of Ochiai

Applicant asserts the rejection fails to cure the deficiencies of the previous rejection made in view of the Bergmann/Flick references. The arguments are moot as the Bergmann/Flick rejection has been withdrawn.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Thursday, from 8:00AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gina C. Yu/

Primary Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/

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